



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Cirillo, P., et al) Art Unit: 1625
U.S. Appln. No. : 10/789,354) Examiner: Desai, Rita
Confirmation No. : 9059
U.S. Filing Date : February 27, 2004
Title of Invention : Cytokine Inhibitors
Attny. Docket No. : 9/276

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

August 18, 2005

**TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT**

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

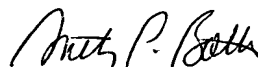
☐ The fee set forth in 37 C.F.R. §1.17(p).

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Respectfully submitted,



Anthony P. Bottino
Attorney for Applicant(s)
Reg. No. 41,629


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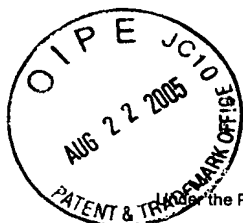
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Anthony P. Bottino, Reg. No. 41,629



PTO/SB/08b (08-03)
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/789,354	
			Filing Date	2/27/2004	
			First Named Inventor	Pier Francesco CIRILLO	
			Art Unit	1625	
			Examiner Name	Rita J. Desai	
Sheet	1	of	4	Attorney Docket Number	9/276

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Tumor Necrosis Factor Inhibitors"; Early Alert Report, Fall 2000	
		van HEEL, D. A ET AL; "Inflammatory bowel disease is associated with a TNF polymorphism that affects an interaction between the OCT1 and NF-kB transcription factors"; Human Molecular Genetics (2002): 1281-1289	
		WEBB, G. R., ET AL; "Chondrocyte tumor necrosis factor receptors and focal loss of cartilage in osteoarthritis"; Osteoarthritis and Cartilage, 1997, 5, 427-437	
		RAINE, C. S. ET AL; "Multiple sclerosis: expression of molecules of the tumor necrosis factor ligand and receptor families in relationship to the demyelinated plaque"; Rev. Neurol. (Paris) 1998, 154, 577-585	
		MA, J. J. ET AL; "Genetic Contribution of the Tumor Necrosis Factor Region in Guillain-Barré Syndrome"; Annals of Neurology, 1998, 44, 815-818	
		CHODOROWSKA, C. ET AL; "Plasma concentrations of IFN-gamma and TNF-alpha in psoriatic patients before and after local treatment with dithranol ointment"; J. Eur. Acad. Dermatolgy And Venereology, 1998, 10, 147-151	
		NAGLER, A. ET AL; "Dysregulation of inflammatory cytokines in unrelated bone marrow transplantation"; Cytokines, Cellular & Molecular Ther., 1998, 4, 161-167	
		ROBAK, E., "Association of Interferon gamma, Tumor Necrosis Factor alpha and Interleukin 6 Serum Levels with Systemic Lupus Erythematosus Activity"; Archivum Immunologiae et Therapiae Experimentalis, 1998, 46, 375-380	
		TASHIRO, H. ET AL; "Role of cytokines in the pathogenesis of restenosis after percutaneous transluminal coronary angioplasty"; Coronary Artery Disease, 12: 107-113	
		BROWN, G. R. ET AL; "Lymphoid Hyperplasia, CD45RBhigh to CD45RBlow T-cell imbalance, and suppression of Type I diabetes mellitus result from TNF blockade in NOD-NOD-scid adoptive T cell transfer"; Diabetologia, 1998, 41, 1502-1510	

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		SOLTYS, J. ET AL; "Modulation of Endotoxin- and Enterotoxin-Induced Cytokine Release by In Vivo Treatment with beta-(1,6)-Branched beta-(1,3)-Glucan"; Infection and Immunity, 1999, 244-252		
		BJUGSTAD, K. B. ET AL; "Preventive actions of a synthetic antioxidant in a novel animal model of AIDS dementia"; Brain Research, 1998, 795, 349-357		
		CHOU, R. C. ET AL; "Adrenergic regulation of macrophage-derived tumor necrosis factor-alpha generation during a chronic polyarthritis pain model"; J. Neuroimmunol., 1998, 82, 140-148		
		MUELLER, G. ET AL; "Is Cytokine Expression Responsible for Differences Between Allergens and Irritants?"; American J. of Contact Dermatitis, Vol. 7, No. 3 (September), 1996, 177-184		
		ELHAGE, R. ET AL; "Differential Effects of Interleukin-1 Receptor Antagonist and Tumor Necrosis Factor Binding Protein on Fatty-Streak Formation in Apolipoprotein E-Deficient Mice"; Circulation, 1998, 97:242-244		
		RYFFEL, B. ET AL; "Failure to induce anti-glomerular basement membrane glomerulonephritis in TNFalpha/beta deficient mice"; Int. J. Exp. Path., 1998, 79, 453-460		
		MITSUI, Y. ET AL; "The expression of proinflammatory cytokine mRNA in the sciatic-tibial nerve of ischemia-reperfusion injury"; Brain Research, 844 (1999), 192-195		
		LI, D. ET AL; "Kinetics of tumor necrosis factor alpha in plasma and the cardioprotective effect of a monoclonal antibody to tumor necrosis factor alpha in acute myocardial infarction" Amer. Heart Journal, 1999, 137, 1145-1152		
		YEH, F. L. ET AL; "Changes in serum tumor necrosis factor-alpha in burned patients"; Burns, 1997, 23, 6-10		
		RENZETTI, L. M. ET AL; "Ro 45-2081, a TNF receptor fusion protein, prevents inflammatory responses in the airways"; Inflamm. Res. 1997, 46, Suppl. 2, S143-S144		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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4

Complete if Known

Application Number 10/789,354

Filing Date 2/27/2004

First Named Inventor Pier Francesco CIRILLO

Art Unit 1625

Examiner Name Rita J. Desai

Attorney Docket Number 9/276

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		LEMAY, S. ET AL; "Prominent and Sustained Up-regulation of gp130-Signaling Cytokines and of the Chemokine MIP-2 in Murine Renal Ischemia-Reperfusion Injury"; Transplantation, Vol. 69, No. 5, (2000), 959-963	
		BOERJESSON, A. ET AL; "TNF-alpha stimulates alveolar liquid clearance during intestinal ischemia-reperfusion in rats"; Am. J. Physiol. Lung Cell. Mol. Physiol., (2000) 278:L3-L12	
		KUROKOUCHI, K. ET AL; "TNF-alpha Increases Expression of IL-6 and ICAM-1 Genes Through Activation of NFkB in Osteoblast-like ROS17/2.8 Cells"; J. Bone and Mineral Res., 1998, 13, 1290-1299	
		HIGHAM, M. A. ET AL; "Tumour necrosis factor-alpha gene promoter polymorphism in chronic obstructive pulmonary disease"; Eur. Respir J. 2000, 15:281-284	
		TAKABATAKE, N. ET AL; "The Relationship between Chronic Hypoxemia and Activation of the Tumor Necrosis Factor-alpha System in Patients with Chronic Obstructive Pulmonary Disease"; Am. J. Respir. Crit. Care Med., Vol. 161, 2000, 1179-1184	
		LEE, T. H.; "Cytokine networks in the pathogenesis of bronchial asthma: implications for therapy"; J. of the Royal Coll. of Phys. of London, Vol. 32, No. 1, Jan/Feb. 1998; 56-64	
		LIPTON, J. M. ET AL; "Peptide Modulation of Inflammatory Processes within the Brain"; Neuroimmunomodulation, 1998, 5, 178-183	
		BRANGER, J. ET AL; "Anti-Inflammatory Effects of a p38 Mitogen-Activated Protein Kinase Inhibitor During Human Endotoxemia"; J. Immunol. 2002, 168: 4070-4077	
		VISCARDI, R. M. ET AL; "Inflammatory Cytokine mRNAs in Surgical Specimens of Necrotizing Enterocolitis and Normal Newborn Intestine"; Pediatric Pathol. And Lab. medicine, 1997, 17, 547-559	
		PARIS, M. M. ET AL; "The Effect of Interleukin-10 on Meningeal Inflammation in Experimental Bacterial Meningitis"; J. Infectious Dis. 1997, 176, 1239-1246	

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